K090648

5. 510(K) SUMMARY

Submitter: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

JUN 10 2009

Contact Person: Frank Jurczak
Regulatory Affairs Associate
Voice: (508) 828-3288
Fax: (508) 828-3797
E-Mail: fjurczak@its.jnj.com

Date Prepared: March 9, 2009

Device Class: Class III

Classification Name: Spinal interlaminar fixation orthosis
per 21 CFR §888.3050

Spinal intervertebral body fixation orthosis
per 21 CFR §888.3060

Pedicle screw spinal fixation
per 21 CFR §888.3070

Classification Panel: Orthopedics

FDA Panel Number: 87

Product Code(s): NKB, KWQ, KWP, MNH, MNI

Proprietary Name: VIPER™2 System

Predicate Devices: EXPEDIUM™ Spine System (K082942, K033901, K041119, K073364)
VIPER System (K071860, K061520, K041801)
MOSS MIAMI Spine System (K933881, K962628, K983583)

Device Description: The subject VIPER2 Spine System components consist of 5.5mm screws and rods and are available in various geometries and sizes.

Intended Use: The VIPER Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the

K090648

treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The VIPER Systems are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used in a percutaneous approach with MIS Instrumentation, the VIPER Systems are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

The PEEK rods of EXPEDIUM Spine System and VIPER Systems are contraindicated for degenerative disc disease.

Materials: Manufactured from ASTM F 138 implant grade stainless steel, ASTM F 136 implant grade titanium alloy, and ASTM F 1537 implant grade cobalt-chromium-molybdenum alloy.

Performance Data: Performance data per ASTM F 1717 were submitted to characterize the subject VIPER2 System components addressed in this notification.

page 2 of 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Spine Incorporated
% Mr. Frank Jurczak
Associate II, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

JUN 10 2009

Re: K090648
Trade/Device Name: VIPER™ 2 System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: III
Product Code: NKB, KWQ, KWP, MNH, & MNI
Dated: May 12, 2009
Received: May 13, 2009

Dear Mr. Jurczak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing

(reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K090648

Device Name: VIPER™2 System

Indications For Use:

The VIPER Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The VIPER Systems are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used in a percutaneous approach with MIS Instrumentation, the VIPER Systems are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

The PEEK rods of EXPEDIUM Spine System and VIPER Systems are contraindicated for degenerative disc disease.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090648

page 1 of 1